



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,767	02/23/1998	WERNER WEITSCHIES	SCH1526	9325
23599	7590	11/25/2003	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			DO, PENSEE T	
		ART UNIT		PAPER NUMBER
		1641		

DATE MAILED: 11/25/2003

33

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/894,767	WEITSCHIES ET AL.
	Examiner Pensee T. Do	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 05 September 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-3,5-18,22-32 and 35-42 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 3, 6, 7, 22, 27-31, 35 is/are allowed.

6) Claim(s) 1,2,5,8-18,23-26,32 and 36-42 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 30.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

The request filed on September 5, 2003 for a Continued Examination (RCE) under 37 CFR 1.114 is acceptable and an RCE has been established. An action on the RCE follows.

#### ***Election/Restrictions***

Applicant's petition of restriction requirement has been granted. Thus, all the previously withdrawn claims are rejoined.

Claims 1-3, 5-18, 22-32, 35-42 are rejoined.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5, 8-18, 23-26, 32, 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all dependent claims, please change "A process" in line 1, to --The process-- for proper antecedent basis.

Claims 1 and 2 lack determination step. There is no positive recitation of a contact step between reagents and sample or a correlation step that relates the remanence magnetization to the presence of analyte. The claims are also unclear as to what is being detected to determine the presence of analyte. The claims only recite "determining remanence magnetization" which has no association with the presence of

analytes. The claims are also unclear as to how the magnetization determines the presence of analyte, e.g. detecting a rise or drop in this magnetization to detect the analytes.

Claim 40 lack antecedent support for the structure-specific substances" which has not been introduced in claim 1.

#### ***Response to Arguments***

Applicant's arguments filed September 5, 2003 have been fully considered but they are not all persuasive.

Regarding claims 1-2 which have been rejected for not having method steps, Applicants submit that "determining remanence magnetization of a ferromagnetic or ferromagnetic substance, bound to analyte" is sufficient for a method step. This step can be conducted without separation of these unbound markers, which is a significant advance over the art. The analyte and magnetic substance are previously bound, and thus a contact step is neither necessary nor desired in these claims. The claims are complete as is.

"Method claims need not recite all operating details but should at least recite positive, active steps so that claim will set out and circumscribe particular area with reasonable degree of precision and particularity," *In re Moore*, 58 CCPA 1042, 439 F.2d 1232, 169 USPQ 236 (1971) "and make clear what subject matter claims encompass," *In re Hammack*, 57 CCPA 1225, 1230, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (1970), "as well as clear subject matter from which others would be precluded", *In re Hammack, supra*, 57 CCPA at 1231, 427 F.2d at 1382, 166 USPQ at 208. The claims

fail to recite a positive, active correlation step that relates the remanence magnetization to the presence of analyte. The claims are also unclear as to how the magnetization determines the presence of analyte, e.g. detecting a rise or drop in this magnetization to detect the presence of analytes.

**Remarks**

Claims 1-3, 5-18, 22-32, 35-42 are free of prior arts.

The prior arts do not teach a method of qualitative and/or quantitative detection of analytes in a liquid and/or solid phase homogeneous assay, comprising determining the remanence magnetization in said homogeneous assay after addition to a sample of a stable or quasi-stable ferromagnetic or ferromagnetic substances.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do  
Patent Examiner  
November 13, 2003

*Christopher L. Chin*  
CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1600/641